BARBARA A. NIKSCH

4 Jenner Suite 180, Irvine CA 92618 949-341-0700 bniksch@visiogeninc.com

Educational Background

1991 Master's in Business Administration, National University, Irvine, California
1987 Bachelor's of Science in Cellular and Molecular Biology, University of Nevada, Reno.

Employment Experience

Visiogen, Inc. Irvine, California (February 2005 to present)
Vice President, Regulatory, Quality and Clinical Affairs
Member of the Sr. Staff at Visiogen, a start-up medical device company working in the accommodating intraocular lens field, and responsible for overseeing all Regulatory, Quality and Clinical activities conducted in the company.

Glaukos Corporation, Laguna Hills, California (March 2001 - January 2005)
Vice President, Regulatory, Quality and Clinical Affairs
As a member of the founding management team (3rd employee), responsible for directing all Regulatory Affairs, Quality Assurance and Clinical Research activities at Glaukos Corporation, a start-up medical device company developing implantable intraocular devices for the treatment of open-angle glaucoma. The Regulatory aspects of this position included recommending and implementing worldwide regulatory submission strategies, negotiating strategies with regulatory bodies, forming and presenting strategies to the scientific advisory boards, and submission of applications to worldwide regulators to seek clinical study initiation. The Clinical aspects of this position focused on the design of clinical strategies and studies and all associated activities related to complete implementation. Generation of clinical documentation, recruitment of key opinion leaders for investigators and collaborators, conducting investigator training sessions, and all aspects of clinical study maintenance were conducted and/or directed by this position. This position acted as the designated management representative responsible for establishing and maintaining the quality system elements within Glaukos. In addition, this position worked with other team members to ensure design control activities were thoroughly completed in order to meet the requirements of ISO 9001, ISO 13485, and 21 CFR 820.

Allergan, Inc., Irvine, California (August 1992 – March 2001)
Manager, Worldwide Regulatory Affairs and Medical Compliance. Responsibilities included management of worldwide product registrations and postmarket surveillance activities for Class 1, 2 and 3 medical devices (e.g., intraocular lenses, viscoelastic solutions, and phacoemulsification surgical equipment) and generic pharmaceuticals (balanced salt solutions). Submission experience included 510(k)'s, original PMA's, PMA supplements, IDE's, CE marking and various international registrations. Specific responsibilities included the independent development of worldwide regulatory strategies, accurate interpretation of new and existing worldwide regulations, support of pre and post approval FDA, state or ISO inspections, participation in R&D and operations project teams (including business teams) to provide thorough regulatory guidance, review of promotional material and labeling, and sales representative training in the area of regulatory requirements. Auditing of subcontractors and manufacturing sites was also within scope of responsibility. Position was responsible for hiring, training and managing staff to ensure fulfillment of worldwide government requirements, timely receipt of registration approvals for marketing new products, maintenance of market approvals for existing products, and appropriate investigation, trending, and reporting of product complaints.

Baxter Healthcare Corporation, Edwards Cardiovascular Surgery Division, Irvine, California
(June 1989 – August 1992)
Regulatory Affairs Specialist. Responsibilities included both post market surveillance activities as well as global product registrations for cardiovascular surgery devices. Responsibilities included trend analyses, evaluation of explanted heart valves, correspondence with surgeons and patients, U.S. and international registration of Class 1, 2 and 3 medical devices, and R&D project team participation during feasibility and developmental phases of new medical devices. Training of new laboratory personnel, creation of department procedures, and database administration were also key responsibilities.

ASI Systems International, Orange, California (June 1987 – February 1989)

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Scientific Programmer, Engineering Staff. Responsible for statistical analyses, Fortran and C programming, and the graphical representation of data obtained from classified government projects.

Professional Affiliations

Past President, OCRA (Orange County Regulatory Affairs Discussion Group), July 2005 – Present
Board of Directors for OCRA 2001-present (CFO 2001-2003, President Elect 2003-2004, President 2004-2005)
Regulatory Affairs Professional Society (RAPS) - Chairperson, RAPS Ethics Committee (2004-present)
Association of Clinical Research Professionals (ACRP)
Association for the Advancement of Medical Instrumentation (AAMI)
Forum for Women Entrepreneurs (FWE); Chairperson, Life Sciences Special Interest Group
Ophthalmic Women Leaders (OWL)

Presentations

Invited Speaker at Regulatory Affairs Professional Society (RAPS) Seminar – Compliance with US Regulatory Requirements: FDA Inspections, Santa Monica, CA (01/2000)

Invited Speaker at RAPS Seminar - The Critical Role of Regulatory in Small and Start-Up Companies: 2002 Medical Device Conference, San Francisco, CA (03/2002)

The Impact of Medical Device User Fee and Modernization Act (MDUFMA, HR 5651); An Industry Perspective. The Orange County Regulatory Affairs Discussion Group, Irvine, CA (12/2002).

Invited Speaker at RAPS Seminar and Program Committee Member - Critical Issues in Small and Start-Up Companies, San Francisco, CA (01/2003)

Invited Speaker at various USC Master's Program Courses (2003-2004)

Invited Speaker at Whittier Law School Seminar – Freedom to Operate: Identifying a Clear Field and Keeping it – A Small company perspective (04/2005)

Publications/Scientific Posters

Poster, ARVO 2005: Co-Existent Open-Angle Glaucoma and Cataract: Treatment by Cataract Surgery and the iStent™ Trabecular Bypass Micro Stent

Relevant Training/Courses

- Attended numerous physician's courses at the American Academy of Ophthalmology and American Society for Cataract and Refractive Surgery professional meetings (1992 -2005)
- Multiple Field visits with Ophthalmic Surgeons (1993-2005)
- American Society for Quality Control – Techniques for FDA Regulatory Submissions
- Rapid Product Development Training (conducted by Cal Tech)
- FDLI (Food and Drug Law Institute) - Understanding Government Regulation of the Marketing and Advertising of Medical Devices, Drugs and Biologics
- FDA Videoconference – Clinical Trials and Statistics
- Design and Process Validation Training (5 days of coursework)
- Negotiating Skills (Cal Tech course)